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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,683	08/07/2001	Heinrich Decker	38005-0152	9675

26633 7590 06/02/2003

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/922,683

Applicant(s)

DECKER, HEINRICH

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 34-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/194,905.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 34-37 are now currently pending in this application.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Claim Objections

Claims 35 and 37 are objected to because of the following informalities: Claims 35 and 37 do not recite biological species names in italics. Appropriate correction is required.

Claim 36 (i) is objected to because of the following informalities: Claims 36(i) recites the word "natural" with incorrect spelling. Appropriate correction is required.

Claim 37 is objected to because of the following informalities: Claims 37 recites the name "Actinoplanes" with incorrect spelling. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 34 recites the phrase "expressing DNA". This leads one to believe that acarbose can be prepared by expressing "any DNA". Even though applicants limit the type of DNA that needs to be expressed in the next step, amending the claim to recite "expressing a DNA" would render the claim clear.

Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 36 is directed to a process of preparing acarbose comprising the steps of "eliminating DNA in a natural acarbose-producing host cell" followed by isolating the acarbose. First of all it is not clear to the Examiner whether all the DNA of the host cell is eliminated or only specific DNA as recited in following steps is eliminated. Secondly it is not clear to the Examiner as to how after elimination either all of the host DNA or elimination of only specific DNA sequences of the host cell involved in acarbose synthesis leads to production of acarbose. It appears that the step of transforming such host cells with DNA responsible for acarbose synthesis is missing.

Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: transformation of the host cell with DNA

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encoding the acarbose synthesizing enzymes followed by culturing of such transformants and isolation of the accumulated acarbose.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of preparing acarbose comprising the steps of transforming a host cell (either before or after eliminating native acarbose synthesizing genes) with a suitable expression vector comprising SEQ ID NO:7 (comprising all the DNE sequences essential for encoding acarbose synthesizing enzymes), followed by culturing the transformant under conditions such that the transformed genes are expressed and acarbose is synthesized and isolation of the accumulated acarbose, does not reasonably provide enablement for a method of producing acarbose by simply expressing one or more fragments of SEQ ID NO:7 (as in claim 34) or for a process comprising isolating acarbose from the culture supernatants of host cell in which the native acarbose synthesizing genes are all eliminated (as in claims 36-37). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the

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prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 34-37 are so broad as to encompass a method of making acarbose by transforming or expressing one or more specific fragments of SEQ ID NO:7 and a method of making acarbose wherein the native acarbose genes are eliminated. The scope of the claims is not commensurate with the enablement provided by the disclosure. It appears that the entire sequence of SEQ ID NO:7 is required to encode all the enzymes involved in the synthesis of acarbose. Furthermore, applicants have not shown that one can synthesize acarbose by expressing one or more specific fragment of SEQ ID NO:7. On the same lines, applicants have also not shown that they were able to make acarbose by culturing host cells in which native genes involved in acarbose synthesis, if any, were eliminated. Applicants have not taught as to how such strains can function and produce acarbose without transforming them with vectors comprising acarbose synthesizing genes such as SEQ ID NO:7. For the claimed methods to be enabled, there is a requirement of knowledge and guidance with regard to how such experiments can be performed. However, in this case the disclosure is limited to the production of acarbose from transformants cultured such that the transformed DNA comprising SEQ ID NO:7 is fully expressed and acarbose is produced. It would require undue experimentation of the skilled artisan to make and use the claimed acarbose with an undefined method. The specification is limited to teaching use of SEQ ID NO: 7 as involved in acarbose synthesis but provides no guidance with regard to the making of acarbose using fragments of SEQ ID NO:7. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in

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predicting function from a polynucleotide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the method encompassed by these claim.

The specification does not support the broad scope of the claims which encompass all above methods because the specification does not establish: (A) that one or more specific fragments can be successfully used for transformation and synthesis of acarbose; (B) a rational and predictable scheme for eliminating native acarbose genes with an expectation of obtaining the desired biological function; and (C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, the claimed method of making acarbose is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 34-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. These claims are directed to a method of making acarbose using/eliminating a genus of DNA molecules.

The specification does not contain any disclosure of the function of all DNA sequences that are fragments of SEQ ID NO:7 in the context of the claimed method. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species (SEQ ID NO:7) of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Sequence compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that applicants fail to provide appropriate SEQ ID NO in claims. While the sequences recited in claims is referred back to the Table 4, Examiner notes that table 4 does not indicate the start and stop of each of the recited sequences and does not identify as to which SEQ ID NO refer to DNA and which refers to proteins. See particularly 37 CFR 1.821(d).

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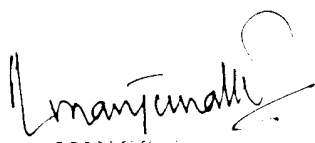
Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.


MANJUNATH N. RAO
PATENT EXAMINER

Manjunath N. Rao
May 30, 2003